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EXAMINER

RAMIREZ, JOHN FERNANDO

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/611,838	<b>Applicant(s)</b> SCHAER, ALAN	
	<b>Examiner</b> JOHN F. RAMIREZ	<b>Art Unit</b> 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14, 18-36, 40-44, 46, 50-59 and 63-66 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14, 18-36, 40-44, 46, 50-59 and 63-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/03/08 has been entered.

### ***Response to Arguments***

After a review of applicant's remarks, the examiner of record acknowledges the amendments to the claims on pages 2-8. Accordingly, new claims 63-66 have been added.

Applicant's arguments filed November 3, 2008 have been fully considered but they are not persuasive. Applicant alleges on pages 9-11 of the remarks, that the Shadduck patent does not teach a "cylindrical vibrational transducer to be positioned with an inflated balloon in the body lumen". However, as argued before, the examiner of record disagrees with applicant's comments. Figures 3A, 4, 11A, 7B, of the Shadduck patent shows a cylindrical vibrational transducer to be positioned with an inflated balloon in the body lumen. Additionally, in column 8, lines 17-31; in column 9, lines 8-21; in column 12, lines 29-46; and in column 15, lines 41-46, the specifications of the Shadduck patent specifically states:

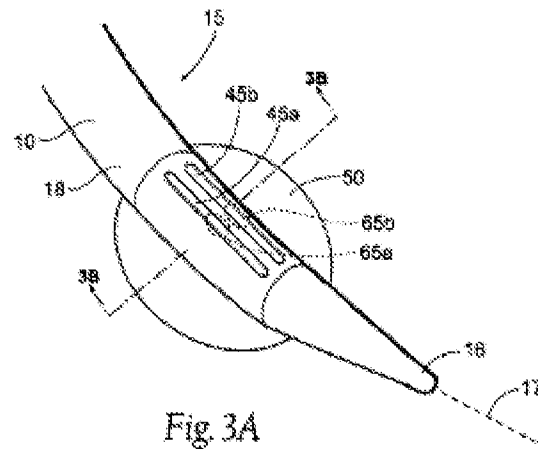


Fig. 3A

Referring to FIG. 3A, the working end 15 carries at least one electrode in an electrode array 44, and preferably carries a plurality of Rf electrodes 45a-45n that are positioned in the surface 46 of working end 15. FIGS. 1 and 3A show two exemplary electrodes 45a-45b arranged longitudinally in extension member 10 in a spaced relationship in surface 46. The electrodes 45a-45b shown in FIG. 3 may be operated in a mono-polar mode (with groundplate) but preferably are operated in a bi-polar mode to provide controlled energy delivery to achieve a particular temperatures between the adjacent paired electrodes 45a-45b in the wall W of the LES proximate to the electrodes. The electrodes are of any suitable biocompatible conductive material which conduct current to and from tissue around the LES in direct contact with electrodes 45a-45b.

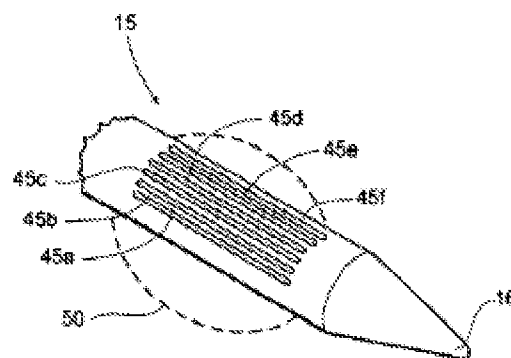
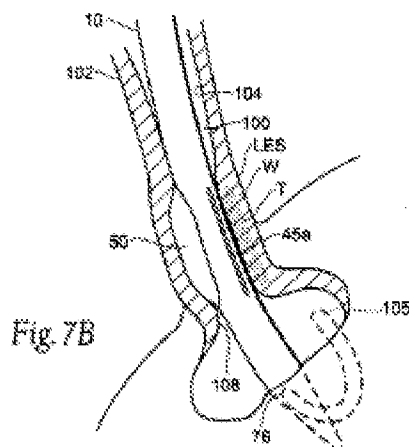


Fig. 4

Art Unit: 3737

shown in FIG. 4. In FIG. 4, the alternative embodiment is shown with six longitudinal electrodes **45a-45b**. The embodiment of FIG. 4 thus may be operated in a mono-polar mode or in a bi-polar mode with a computer controller **60** (see FIG. 1) operatively connected to the Rf source **40** and electrodes and temperature sensors to multiplex (of vector) the current flow between and among various paired electrodes. (It should be appreciated that working end **15** may carry only a single electrode operated in a mono-polar mode and fall within the scope of the invention).

In the preferred embodiment described above, the elongate configuration of the electrodes and their longitudinal orientation was selected because it is believed that Rf energy delivery to elongate regions of the LES will prove optimal to accomplish the objectives of methods of the invention. As



Art Unit: 3737

Referring to FIG. 7B, the diameter of extension member  
 30 **10** may fit somewhat loosely or snugly in esophageal lumen  
**100** depending on the diameter of device selected. As shown  
 in FIG. 7C, the physician preferably (but optionally) inflates  
 balloon **50** with an inflation medium, for example air or  
 saline solution from a syringe (not shown). Balloon **50** is  
 35 inflated to a sufficient dimension to press the surface of  
 working end **15**, and more particularly electrodes **45a** and  
**45b**, into firm contact with surface **104** of targeted tissue in  
 wall **W** of the LES. (It should be appreciated that a flexible  
 fiberscope **105** (phantom view) may introduced through a  
 40 optional working channel **76** to view the gastro-esophageal  
 junction **108** from inside the patient's stomach **110** which  
 may be useful in positioning the device (see FIG. 7B)). The  
 physician selects the treatment site based on anatomical  
 knowledge of the LES and is thus capable of avoiding  
 45 thermal energy delivery to certain areas or sides of the LES  
 if so desired.

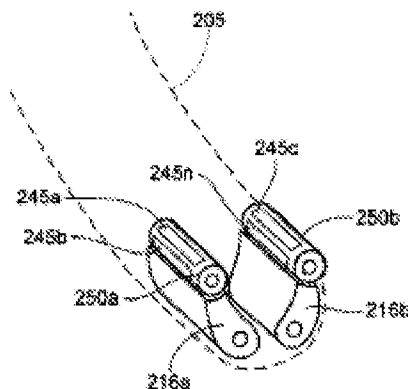


Fig. 11A

FIG. 11A illustrates another embodiment of Type "B" device in which roller elements **250a** and **250b** are carried in arm elements **216a** and **216b** to progressively engage the wall **W** of the LES and deliver RF energy between various paired electrodes **245a**–**245n** in the roller elements **250a** and **250b**. This manner of RF energy delivery was disclosed in

In response to applicant arguments that the Shadduck reference does not describe a device for treating the LES by using ultrasonic energy. The examiner disagrees with applicant's comments as illustrated in the paragraph below from the Shadduck's specifications in column 10, lines 32-51 specifically states:

Another embodiment of a Type "A" device 5 is shown in FIG. 6A wherein an ultrasound source 70 may be coupled to one or more ultrasound transducers 72 (collectively) in a spaced relationship in working end 15 of extension member 10. An output of ultrasound source 70, optionally in combination with Rf source 40, may be adapted to deliver thermal energy to the LES. Each ultrasound transducer 72 may be a piezoelectric crystal mounted on a suitable substrate. A conventional ultrasound lens of electrically insulated material is fitted between the exterior of surface 18 of working end 15 and the piezoelectric crystal which is connected by electrical leads in extension member to ultrasound source 70. Each ultrasound transducer thus is capable of transmitting ultrasound energy into the target tissue of the LES for imaging purposes or high-energy ultrasound (HIFU) to deliver thermal energy. Thermocouples can provide accurate temperature measurements of surface temperatures at various points along the esophageal lumen. Such thermal sensors are preferably adjacent to piezoelectric crystals.

Based on the above evidence, the method disclosed by Shadduck shows and teaches or suggest the use of ultrasonic energy and a "cylindrical vibrational transducer to be positioned with an inflated balloon in the body lumen".

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3737

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

**Claims 1-9, 12-14, 20-23, 40-44, 46, 50-51, 54-56 and 63-66 are rejected under 35 U.S.C. 102(e) as being anticipated by Shadduck (US 6740082).**

Shadduck discloses an instrument and method for treatment of the lower esophageal sphincter. Although much of the disclosure is directed to Rf sources, Shadduck states that other sources of energy such as ultrasound or high-energy focused ultrasound known in the art may be used in place of the Rf source (col 8, lines 10-15). Energy is delivered to a targeted tissue volume to accomplish controlled remodeling of the tissue (col 2, lines 50-52), where the target tissue is an anatomic lumen, such as the esophagus or the urethra (col 2, line 60). The energy electively



Art Unit: 3737

injures cells to induce a biological response, which causes collagen formation (col 3, line 5) and additionally causes ionic agitation (col 3, line 45), and shrinking of tissue (col 3, line 32) including contracting longitudinally (col 4, line 38), which reduces compliance of the tissue. The injury of cells inherently interrupts their normal functions, such as interrupting nerve pathways and the ability to absorb food. Intestinal metaplasia is just one type of tissue found in the esophagus, which may be selectively remodeled by the system and is merely an intended use of the system, which is inherently capable of destroying, specific tissues in the esophagus. Alternative uses disclosed include endoscopically accessing a hiatal hernia in the abdominal cavity (col 17, lines 5-6) where the lumen would be the diaphragmatic sphincter. Energy is used to heat temperature in the range of 40 to 70 degrees Celsius, which is within the range of 55 to 95 degrees (col 3, line 27). A sensor array is used to measure temperature levels of a portion of the wall in contact with the sensor (col 10, line 16-18), wherein the wall consists of more than just the luminal surface. Additionally, temperature measurements of surface temperatures along the lumen surface (col 10, line 50), which can also be used to ensure over a certain maximum temperature is not reached during treatment (col 11, line 18). A cooling means may be circulated to maintain surface of the esophageal lumen (col 17, line 59). An elongate member, or catheter, with a working end is used to introduce the system to the lumen or target tissue (col 7, line 53-55). A balloon made of an elastomeric material is used which is inflatable with a transmissive medium until it contacts the surface of the target tissue in the wall of the LES (col 12, line 29-38). Alternatively, tissue maybe captured between movable opposed elements

Art Unit: 3737

(figure 12A, elements 252a and 252b) with transducers (figure 12A, elements 245a and 245b) that direct energy to the captured tissue. The instrument includes a working channel that allows an endoscope or another instrument to be introduced (col 6, lines 44-45). Shadduck further discloses that the balloon comprises a silicone material (col. 8, lines 41-42) which selectively absorbs acoustic energy to enhance heating at the surface of the balloon (col. 10, lines 32-51), wherein the balloon is attached to a distal end of the cannula (see fig. 3A) and a distal orifice of the cannula is within the balloon (see figs. 2, 3A-B, col. 8, lines 35-49).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shadduck in view of Hutchinson, et al (US 6929608).**

Shadduck, as discussed above, substantially discloses the invention, as claimed, however fails to explicitly disclose the energy range used. Hutchinson teaches that it is well known in the art to use a range from 0 to 30 W/cm<sup>2</sup> (figure 11) for the deposition in body tissue for thermal therapy (col 1). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Shadduck in light of

Art Unit: 3737

the teachings in the reference by Hutchinson in order to use a well-known energy range for proper tissue treatment.

**Claims 11, 24-25 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shadduck in view of Ingle, et al (US 6976492).**

Shadduck, as discussed above, substantially discloses the invention as claimed, however fails to explicitly disclose the duty cycle used and the use of a phased array. Ingle teaches the use of a 50% duty cycle (col 7, lines 26-29), which falls in the range of 10% to 100%, for the improved shrinking of tissues. Additionally, a phased array ultrasound transmitter is used (col 8, lines 50-51). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Shadduck in light of the teachings in the reference by Ingle to include a 50% duty cycle for improved treatment of target tissues and a phased array for enhanced targeting flexibility (col 8, line 50).

**Claims 18, 19, 26, 27, 28, 30-34, 36, 52, 57 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shadduck in view of Chapelon et al (US 5720287).**

Shadduck, as discussed above, substantially discloses the invention as claimed, however fails to disclose details of the relationship between the balloon and the transducer itself. In regards to claims 19 and 27, Shadduck, as previously discussed,

Art Unit: 3737

discloses cooling of the fluid medium in the balloon to cool the luminal surface as well as viewing the target tissue through an endoscope. In regards to claims 30-32,

Shadduck additionally discloses a balloon that is expanded against the body lumen for treatment, including the area adjacent to the opening as well as the entire opening (figures 7a and 7b). Chapelon discloses a therapy probe for ultrasound therapy and further teaches a transducer probe surrounded by a flexible membrane (figure 9, element 120), which is filled with an acoustic-coupling liquid such as water or an oil (col 4, lines 41-44). The transducer is movable with respect to the flexible outer casing of the probe (col 2, line 15-16), which may be focused through pivotal mounting. The probe may be rotated, pivoted, or translated (col 8, lines 14-16) and multiple transducers may be used, exemplarily using one for imaging and one for treatment, as seen in figure 9. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Shadduck in light of the teachings in the reference by Chapelon to include increased mobility of the probe and transducer to advantageously increase the number of target areas able to be reached by the ultrasonic treatment.

**Claim 29 rejected under 35 U.S.C. 103(a) as being unpatentable over Shadduck in view of Chapelon as applied to claim 26 above, and further in view of Makower, et al (US 6302875).**

Shadduck in view of Chapelon, as discussed above, substantially discloses the invention as claimed, however fails to disclose the used of a circumferential array transducer. Makower discloses a system for an ultrasound catheter that may be inserted into blood vessels or other body lumens and further teaches the use of a

Art Unit: 3737

circumferential array (claim 22). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Shadduck in view of Chapelon in light of the teachings in the reference by Makower to include a circumferential array, as a luminal anatomical structure (col 1, line 28) is circumferential and therefore the use of this array will advantageously increase the number of target areas.

**Claim 35 rejected under 35 U.S.C. 103(a) as being unpatentable over Shadduck in view of Chapelon as applied to claim 26 above, and further in view of Jang (US 4744366).**

Shadduck in view of Chapelon, as discussed above, substantially discloses the invention, as claimed, however fails to disclose the used of multiple coaxial balloons. Jang discloses a catheter, which analogously uses balloons to obtain proper placement of the catheter and to provide contact with a lumen wall. Additionally Jang teaches the use of multiple balloons that are independently inflated, and thereby translated, to provide desired positioning (figure 8). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Shadduck in view of Chapelon to include multiple coaxial balloons to provide improved control in positioning the catheter and a greater range of available balloon diameters.

**Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shadduck in view of Makower.**

Art Unit: 3737

Shadduck, as discussed above, substantially discloses the invention as claimed, however fails to disclose the used of a circumferential array transducer. Makower discloses a system for an ultrasound catheter that may be inserted into blood vessels or other body lumens and further teaches the use of a circumferential array (claim 22). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Shadduck in light of the teachings in the reference by Makower to include a circumferential array, as a luminal anatomical structure (col 1, line 28) is circumferential and therefore the use of this array will advantageously increase the number of target areas.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN F. RAMIREZ whose telephone number is (571)272-8685. The examiner can normally be reached on (Mon-Fri) 7:00 - 3:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3737

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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